

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**JUL 24 1996**

Dr. Kent Croon  
Regulatory Affairs Manager  
Monsanto Company  
700 Chesterfield Parkway North  
Chesterfield, Missouri 63198

Dear Dr. Croon:

This is in regard to Monsanto's consultation with the Food and Drug Administration (FDA) (Center for Veterinary Medicine and Center for Food Safety and Applied Nutrition) on genetically modified corn, specifically transformation event MON801. According to Monsanto, this new corn variety has been modified for resistance to the European Corn Borer through expression of the *cryIA(b)* gene from *Bacillus thuringiensis* subsp. *kurstaki*.

On March 10, 1995, Monsanto met with FDA to discuss the proposed safety and nutritional assessment of corn containing transformation event MON801. As part of bringing the consultation regarding this product to closure, Monsanto submitted a summary assessment of corn containing transformation event MON801 on September 15, 1995.

These communications informed FDA of the steps taken by Monsanto to ensure that these products comply with the legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment you have conducted, it is our understanding that Monsanto has concluded that corn grain (kernels), fodder, and silage derived from the new variety are not materially different in composition, safety, and other relevant parameters from corn grain, fodder, and silage currently on the market, and that the genetically modified corn does not raise issues that would require premarket review or approval by FDA. All materials relevant to this notification have been placed in a file designated BNF0018. This file will be maintained in the Office of Premarket Approval.

Based on the information Monsanto has presented, we have no further questions concerning corn containing transformation event MON801 at this time. However, as you are aware, it is Monsanto's responsibility to ensure that foods marketed by the firm are safe, wholesome and in compliance with all applicable legal and regulatory requirements.

Sincerely,

/s/

Alan M. Rulis, Ph.D.

Director

Office of Premarket Approval

Center for Food Safety

and Applied Nutrition

cc:	HFS-200	HFS-205	HFS-226	HFS-235	HFS-246	HFS-247
	HFS-13	HFS-144	HFV-200	HFV-221	HFV-226	BNF0018
	HFS-206					